A Survey of Experiences and Opinions Regarding Skin Toxicities Associated with Vectibix Among mCRC Patients

First published: 30/07/2019

Last updated: 11/11/2020

Study Finalised

Administrative details

EU PAS number

EUPAS30334

Study ID

38009

DARWIN EU® study

No

Study countries

☐ United States

Study description

This descriptive study is designed with the primary objective of assessing experiences and opinions regarding dermatologic toxicities that may develop among mCRC patients who are treated with and without Vectibix.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Contact details

Study institution contact

Global Development Leader Amgen Inc.

medinfo@amgen.com

Study contact

medinfo@amgen.com

Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/03/2019

Actual: 15/03/2019

Study start date
Planned: 01/11/2019

Actual: 01/11/2019

Data analysis start date
Planned: 01/01/2020

Actual: 15/11/2019

Date of final study report
Planned: 30/06/2020

Actual: 11/11/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

csr-20190025-protocol_public-redacted-approved-version.pdf(926.35 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Primary data collection

Main study objective:

To assess the experiences and opinions regarding dermatologic toxicities that may develop among mCRC patients who are treated with and without Vectibix.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Name of medicine

VECTIBIX

Medical condition to be studied

Skin toxicity

Population studied

Short description of the study population

Patients needed to be at least 18 years of age, have a diagnosis of metastatic colorectal cancer (mCRC) and provide consent to participate.

Inclusion Criteria

1. 18 years of age or older

2. Have a self-reported physician diagnosis of mCRC

3. Have consented to participate

Exclusion Criteria

Patients not meeting inclusion criteria will be excluded. Additional exclusion criteria include treatment with cetuximab at any point.

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Metastatic colorectal cancer (mCRC) patients

Estimated number of subjects

200

Study design details

Outcomes

Among mCRC Vectibix patients• Describe mCRC patient opinions regarding the risk of skin • Characterize the timing and severity of rash • Describe the education they received to prevent and manage rash • Describe management strategies • Describe the impact on quality of lifeAmong mCRC non-Vectibix

patients • Describe patient opinions regarding the risk of skin rash

Data analysis plan

The following descriptive statistics will be analyzed:• Proportion of mCRC patients who agree to participate in the study• Proportion of mCRC patients who meet the criteria for participation (i.e. eligibility rate)The consent rate will be calculated as the proportion of eligible patients who consent to participate in the survey out of all eligible patients.

Documents

Study results

20190025_Adelphi ORSR_08.24.20_abstract (002)_Redacted.pdf(38.69 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No